Exhibit A

2/27/06 Chain Drug Rev. 69
2006 WLNR 3617342

Chain Drug Review

February 27, 2006

Volume 28; Issue 4

Hopes high as 72 drugs are set to lose patents.

NEW YORK -- Blockbuster medicines ranging from A to Z are expected to lose patent protection this year, paving a potentially profitable path for generic drug manufacturers.

All together, 72 branded drugs are expected to lose patent protection this year. Among the products that are set to see patents expire are Ambien (a sleep aid from sanofi-aventis), Pravachol and Zocor (cholesterol medications marketed by Bristol-Myers Squibb Co. and Merck & Co., respectively), and Zoloft (Pfizer Inc.'s antidepressant).

Still, although several products are expected to debut as generics in 2006, the industry itself will experience increased competition, cautions David Maris, an analyst with Banc of America Securities.

Merrill Lynch & Co. analysts anticipate that brands with more than $22 billion in annual sales in the United States could encounter first-time competition from generics this year.

According to an analysis of prescription claims released by Medco Health Solutions Inc., total generic dispensing rates for Allegra, Arava, Amaryl and Zithromax exceeded 87% within 30 days after the brand name counterparts became available. The average generic fill rate at retail pharmacies for the group was over 86%; the rate averaged 95% at the pharmacy benefits manager's mail-service pharmacies.

Each drug lost its patent within the last four months of 2005. Zithromax, the most recent (and largest) of the four to move off patent, scored a generic dispensing rate at retail of more than 90% during the first week of January.

Medco maintains that the availability of generic versions of the four drugs holds the potential to save its clients and their members about $130 million annually.

"Medco regularly achieves a near-95% substitution rate within the first week for

new generic chronic care medications dispensed through our mail-order pharmacies," notes Glenn Stettin, senior vice president of clinical products. "However, the fact an acute care medication like Zithromax (an antibiotic primarily used to treat respiratory infections) is now showing a 90% substitution rate at retail is extraordinary and speaks volumes about the acceptance of physicians to prescribe, pharmacists to dispense and patients to use generic medications."

Medco research indicates that 70 brand name drugs, collectively accounting for more than $45 billion in U.S. sales, could become available as generics within the next five years.

Besides products from traditional pharmaceutical companies, human growth hormone, insulin and other powerhouse biologics will open up to billions of dollars' worth of generics competition over the next several years, according to Kalorama Information.

Nevertheless, warns Kalorama, hurdles for such generics could prove significant with anticipated resistance from innovator companies --particularly from those whose proprietary products generate sales exceeding $1 billion annually. Besides fighting to protect their vested interests, biotechnology companies are likely to present strong cases before regulators relating to the safety and efficacy of such high-tech drugs.

"While the market potential is huge, the area of generic biologic participation is an extremely complex one involving many variables--with safety being the paramount issue," notes Mary Anne Crandall, author of a Kalorama report on the market for generic biologics. "Many stumbling blocks could preclude generic participation in production of biologic products, including access to innovators' key intermediates, process controls, specially designed and adapted analytical procedures, and validation studies."

Still, Kalorama claims that the international biogenerics market could reach $6.6 billion by 2010, with over 61% of this potential market derived from drugs that are now under patent protection.

In January a panel representing European regulators threw its backing behind what could become the continent's first biogeneric. The European Medicines Agency's committee for medicinal products for human use offered an endorsement of Novartis AG's (Sandoz Inc.'s) generic growth hormone Omnitrope. Europe issued guidelines for biogeneric drugs in 2004.

Separately, Sandoz has filed a lawsuit against the Food and Drug Administration for delaying approval of the biogeneric in the U.S.

Generic Substitution Rates

More than half of all prescriptions dispensed in the United States

are generic medicines, but they account for only 12% of

pharmaceutical costs.

'84 19%

'95 43%

'96 43%

'97 44%

'98 46%

'99 47%

'00 47%

'01 49%

'02 51%

'03 51%

'04 53%

Note: Table made from bar graph.

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END OF DOCUMENT

Exhibit B

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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary

In the Matter of **BRISTOL-MYERS SQUIBB COMPANY,** a corporation.	**Docket No. C-4076**

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices by Respondent Bristol-Myers Squibb Company ("Respondent BMS" or "Respondent"), and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and

consideration of public comments, now in further conformity with the procedure prescribed in Commission Rule § 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent BMS is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at 345 Park Avenue, New York, N.Y. 10154.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that for the purposes of this Order, the following definitions shall apply:

A. "Respondent BMS" means Bristol-Myers Squibb Company, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Bristol-Myers Squibb Company, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. "Commission" means the Federal Trade Commission.

C. "180-day Exclusivity Period" means the period of time established by 21 U.S.C. § 355(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355 *et seq.*).

D. "6-Hydroxy-Metabolite of Buspirone" means 6-hydroxy-8-[4-[4-(2- pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione.

E. "30-Month Stay" means the period of time, established by 21 U.S.C. § 355(j)(5)(B)(iii), during which the FDA may not grant final approval to an ANDA.

F. "AB-rated Generic Version" means an ANDA found by the FDA to be bioequivalent to the Referenced Drug Product, as defined under 21 U.S.C. § 355(j)(8)(B).

G. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1, or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

H. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).

I. "ANDA Filer" means a person who has filed or submitted an ANDA with the FDA.

J. "ANDA First Filer" means the person whom the FDA determines is and remains entitled to, or eligible for, a 180-day Exclusivity Period that has not expired.

K. "ANDA Product" means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.

L. "Applicable Law" means the statutes and regulations governing Orange Book listings, including, but not limited to, 21 U.S.C. § 355(b)(1) and (c)(2) and 21 C.F.R. § 314.53(b) and (c).

M. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution), as defined in 21 C.F.R. § 314.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

N. "Encourage" means suggest, advise, pressure, induce, attempt to induce, prompt, or otherwise influence.

O. "Exclusive License" means a license of intellectual property that (a) restricts the right of the licensor to license the intellectual property to other persons, (b) reduces the incentives of the licensor to license the intellectual property to other persons, or (c) grants to the licensee the right to enforce the intellectual property rights against other persons.

P. "Expiration Date" means 180 days after the date that the ANDA First Filer commences commercial marketing of (1) the ANDA Product, (2) the Reference Drug Product, or (3) any other AB-Rated Generic Version of the Reference Drug Product.

Q. "FDA" means the United States Food and Drug Administration.

R. "Listing Information" means any statement or information of any type provided to the FDA in furtherance of the listing or continued listing of any patent in the Orange Book,

however communicated or recorded and regardless of the subject matter, including, but not limited to, any factual or legal subject matter.

S. "Material Patent Information" means any statement or information of any type, however communicated or recorded, regardless of the subject matter, that is material to patentability, as defined in 37 C.F.R. § 1.56(b).

T. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b), including all changes or supplements thereto which do not result in the submission of a new NDA.

U. "NDA Holder" means: (1) the person that received FDA approval to market a Drug Product pursuant to an NDA, (2) a person owning or controlling the ability to enforce the patent(s) listed in the Orange Book in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors, and assigns of each of the foregoing.

V. "Orange Book" means the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations."

W. "Patent Infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, or patents of addition and extensions thereof.

X. "Patent Infringement Claim" means any allegation, whether threatened or included in a complaint filed with a court of law, that an ANDA Filer's ANDA or ANDA Product may infringe any U.S. patent held by, or exclusively licensed to, the NDA Holder of the Reference Drug Product.

Y. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

Z. "PTO" means the United States Patent and Trademark Office.

AA. "Reference Drug Product" means the Drug Product identified by the ANDA Filer as the Drug Product upon which the ANDA Filer bases its ANDA.

BB. "Relinquish" includes, but is not limited to, abandoning, waiving, or relinquishing.

CC. "Sale of Drug Products" means the sale of Drug Products in or affecting commerce, as commerce is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

DD. "Taxol" means any paclitaxel drug product as BMS sold it as of October 1, 2002, including, but not limited to, active ingredient and formulation.

EE. "Taxol Patent" means one or more of (i) U.S. Patent No. 5,670,537, (ii) U.S. Patent No. 5,641,803, or (iii) any other U.S. patent claiming Taxol as a composition of matter, or any method of using Taxol.

FF. "Use Patent" means a patent claiming an indication, dosage regimen, method of administration, or other condition of use.

II.

IT IS FURTHER ORDERED that Respondent BMS shall not seek, maintain, certify to, or take any other action in furtherance of, the listing or continued listing in the Orange Book of U.S. Patent No. 6,150,365 in connection with any NDA where the active ingredient is buspirone.

III.

IT IS FURTHER ORDERED that Respondent BMS shall not:

A. Make a Patent Infringement Claim that a Taxol Patent is infringed by any Drug Product or the use of any Drug Product where the subject of the Patent Infringement Claim is the making, using, selling, offering to sell, or importing of Taxol; or

B. Receive royalties or other fees from another person pursuant to a license of a Taxol Patent to make, use, sell, offer to sell, or import Taxol.

PROVIDED, HOWEVER, nothing in this paragraph shall preclude BMS from engaging in the conduct described in this Paragraph in connection with a Taxol Patent claiming a method of using Taxol in combination with another oncological active ingredient or a composition of matter patent claiming Taxol in combination with another oncological active ingredient.

IV.

IT IS FURTHER ORDERED that Respondent BMS shall not take any action, or Encourage any other person to take any action, that initiates, maintains, or causes to be initiated or maintained, a 30-Month Stay of FDA approval of any ANDA referencing:

A. NDA No. 018731 (BuSpar); or

B. NDA No. 020262 (Taxol).

V.

IT IS FURTHER ORDERED that Respondent BMS shall not make a Patent Infringement Claim that U.S. Patent No. 6,150,365 is infringed by any Drug Product, or the use of any Drug Product, that contains the active ingredient buspirone, unless the Drug Product also contains the 6-Hydroxy-Metabolite of Buspirone and the Patent Infringement Claim is based on the 6-Hydroxy-Metabolite of Buspirone.

VI.

IT IS FURTHER ORDERED that Respondent BMS shall not seek, maintain, certify to, or take any other action in furtherance of, the listing or continued listing of any patent in the Orange Book where the listing of such patent in the Orange Book violates Applicable Law.

VII.

IT IS FURTHER ORDERED that Respondent BMS shall not, in connection with any patent listed in the Orange Book under any NDA for which Respondent BMS is the NDA Holder, take any action, or Encourage any other person to take any action, that initiates, maintains, or causes to be initiated or maintained, a 30-Month Stay of FDA approval of any ANDA referencing such NDA where:

A. The patent is listed in the Orange Book under such NDA after the filing of any ANDA referencing such NDA;

B. Respondent BMS, in obtaining the patent before the PTO, engaged in inequitable conduct as that term is judicially construed in the context of patent litigation;

C. Respondent BMS provided Listing Information that is false or misleading;

D. Respondent BMS provided Listing Information to the FDA and Material Patent Information to the PTO, where Respondent BMS cannot show that, at the time the statements were made, it had a reasonable belief that the Material Patent Information and the Listing Information were both accurate. A violation of this subparagraph VII.D can be established without the Commission proving whether it is the Listing Information or the Material Patent Information that is inaccurate;

E. The patent is a Use Patent, and at the time of its Orange Book listing, such patent did not claim an approved use of the Drug Product specified in the NDA referenced by such ANDA; or

F. The patent claims (1) a composition of matter that is a metabolite of an active ingredient listed in the NDA referenced by such ANDA, and/or (2) a method of use of such a metabolite.

PROVIDED, HOWEVER, it shall not be a violation of either Paragraph VII.E or VII.F if the following three conditions are met:

(1) the patent listed in the Orange Book contains a claim or portion of a claim distinct from those identified in paragraph VII.E and VII.F ("Additional Claim");

(2) an Orange Book listing based on the Additional Claim does not violate Applicable Law; and

(3) so long as BMS maintains a Patent Infringement Claim that the ANDA Filer infringes the Additional Claim.

VIII.

IT IS FURTHER ORDERED that Respondent BMS shall not make any statements to the FDA that are (1) false and misleading; and (2) material to either the approvability of an ANDA referencing an NDA for which BMS is the NDA Holder, or the sale of any product pursuant to such ANDA.

PROVIDED, HOWEVER, it shall not be a violation of Paragraph VIII if, at the time the statement was made, Respondent BMS had a reasonable belief that the statement was neither false nor misleading.

IX.

IT IS FURTHER ORDERED that Respondent BMS shall not, in connection with a Patent Infringement Claim:

A. Assert any fraudulent or objectively baseless claim, or otherwise engage in sham litigation for the purpose of injuring an ANDA Filer rather than to obtain a favorable outcome to the Patent Infringement Claim.

B. Enforce or seek to enforce any patent that it knows is invalid, unenforceable, or not infringed.

X.

IT IS FURTHER ORDERED that Respondent BMS shall not, without providing prior written notification to the Commission in the manner described in Paragraph XVI ("Notification"), acquire from another person a patent or an Exclusive License to a patent if Respondent BMS seeks or secures the patent's listing in the Orange Book for an NDA which has received FDA approval. For purposes of this Paragraph X only, the term acquire shall exclude the assignment or license of patents to Respondent BMS pursuant to an agreement existing at the time the NDA received FDA approval.

XI.

IT IS FURTHER ORDERED that Respondent BMS shall not, with respect to any patent for which BMS acquires a non-exclusive license from another person (the "Acquisition"), assist in, advise regarding, or act so as to affect in any manner the licensor's or any other person's (1) enforcement of the patent with respect to an ANDA, (2) licensing of the patent to an ANDA Filer with respect to an ANDA, or (3) determination of royalties or other fees paid for the patent by an ANDA Filer with respect to an ANDA.

PROVIDED, HOWEVER, nothing in this paragraph shall prohibit Respondent BMS from engaging in the conduct described in this Paragraph with respect to any ANDA filed with the FDA after the Acquisition, unless such ANDA references the same NDA as an ANDA filed with the FDA before the Acquisition.

XII.

IT IS FURTHER ORDERED that Respondent BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement resolving or settling a Patent Infringement Claim in which:

A. An ANDA Filer receives anything of value; and

B. The ANDA Filer agrees not to research, develop, manufacture, market, or sell, the ANDA Product for any period of time.

PROVIDED, HOWEVER, that nothing in this Paragraph XII shall prohibit:

(1) A resolution or settlement of a Patent Infringement Claim in which:

(a) Respondent BMS is the NDA Holder;

(b) The value received by the ANDA Filer, in the resolution or settlement of the Patent Infringement Claim, is no more than (1) the right to market the ANDA Product prior to the expiration of the patent that is the basis for the Patent Infringement Claim, and (2) the lesser of the NDA Holder's expected future litigation costs to resolve the Patent Infringement Claim or $2 million; and

(c) Respondent BMS has notified the Commission, as described in Paragraph XVI.

(2) Respondent BMS from resolving or settling a Patent Infringement Claim after the Commission, in response to a request by Respondent BMS for an advisory opinion pursuant to Section 1.2 of the Commission Rules of Practice, 16 C.F.R. § 1.2, determines that the settlement Agreement would not raise issues under Section 5 of the Federal Trade Commission Act.

(3) Respondent BMS, without notice to the Commission, from seeking relief unilaterally from a court, including but not limited to, applying for permanent injunctive relief, or seeking to extend or reduce a 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

XIII.

IT IS FURTHER ORDERED that, when Respondent BMS makes a Patent Infringement Claim in which Respondent BMS is the NDA Holder, Respondent BMS shall cease and desist, in connection with the Sale of Drug Products, from being a party to any Agreement in which the ANDA Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that:

A. Could be approved for sale by the FDA pursuant to an ANDA; and

B. Is neither the subject of any written claim or allegation of Patent Infringement nor the subject of a written representation from the ANDA Filer's counsel that the Drug Product would be the subject of such a claim or allegation if disclosed to the NDA Holder.

XIV.

IT IS FURTHER ORDERED that Respondent BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products with respect to which Respondent BMS is an NDA Holder for the Reference Drug Product(s), from being a party to any Agreement in which:

A. One party is an NDA Holder and the other party is the ANDA First Filer for the Reference Drug Product; and

B. The ANDA First Filer is prohibited by such Agreement from Relinquishing, or is subject to a penalty, forfeiture, or loss of benefit, if it Relinquishes its right to the 180-day Exclusivity Period.

PROVIDED, HOWEVER, that nothing in this Paragraph shall prohibit any Agreement if and only if the following three conditions are all met:

(1) Within twenty (20) days of entering into the Agreement, the ANDA First Filer commences commercial marketing of the ANDA Product, the Reference Drug Product, or any other AB-rated Generic Version of the Reference Drug Product;

(2) One of the following two conditions has been satisfied:

(a) the 180-day Exclusivity Period, if any, has been triggered by the commercial marketing required by proviso subparagraph (1) above, and has begun to run with respect to the ANDA Product; or

(b) within ten (10) days of the commercial marketing of a Drug Product other than the one subject to the ANDA, the ANDA First Filer has notified the FDA, in writing, that it will Relinquish any and all eligibility for, and entitlement to, a 180-day Exclusivity Period, if any, for the ANDA Product, beyond the Expiration Date; and

(3) Respondent BMS has notified the Commission, as described in Paragraph XVI.

XV.

IT IS FURTHER ORDERED that, in any instance where Respondent BMS is a party to a Patent Infringement Claim in which it is the NDA Holder, Respondent BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement in which:

C. The parties do not agree to dismiss the litigation;

D. The NDA Holder provides anything of value to the alleged infringer; and

C. The ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the ANDA Product, or any Drug Product containing the same active chemical ingredient as the ANDA Product.

PROVIDED, HOWEVER, such an Agreement is not prohibited by this Order when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 65, if:

(1) Together with the stipulation for a preliminary injunction, Respondent BMS provides the court the proposed Agreement, as well as a copy of the Commission's complaint and order in this matter;

(2) Respondent BMS has notified the Commission, as described in Paragraph XVI, at least thirty (30) days prior to submitting the stipulation for a preliminary injunction;

(3) Respondent BMS does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and

(4) One of the following two conditions apply:

(a) the court issues an order and the parties' agreement conforms to said order; or

(b) the Commission, in response to a request by Respondent BMS for an advisory opinion, pursuant to Section 1.2 of the Commission Rules of Practice, 16 C.F.R. § 1.2, determines that entering into the stipulation would not raise issues under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

PROVIDED, HOWEVER, nothing in this Paragraph XV shall be interpreted to prohibit or restrict the right of Respondent BMS unilaterally to seek relief from the court (including but not limited to, applying for preliminary injunctive relief or seeking to extend, or reduce, the 30-Month Stay).

XVI.

IT IS FURTHER ORDERED that:

A. Respondent BMS shall notify the Commission as required by Paragraphs X, XII, XIV, and XV in the form of a letter ("Notification Letter") submitted to the Secretary of the Commission, which shall contain the following information:

(1) The docket number and caption name of this Order;

(2) A statement that the purpose of the Notification Letter is to give the Commission prior notification of a proposed Agreement as required by this Order;

(3) Identification of the parties involved in the proposed Agreement;

(4) Identification of all Drug Products involved in the proposed Agreement;

(5) Identification of all persons, to the extent known, who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the proposed Agreement;

(6) A copy of the proposed Agreement;

(7) Identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the proposed Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and

(8) All documents which were prepared by or for any officer(s) or director(s) of Respondent BMS for the purpose of evaluating or analyzing the proposed Agreement, *provided that* documents subject to a valid claim of privilege or work product need not be produced pursuant to this provision, but shall be identified in a log.

B. Respondent BMS shall submit the Notification Letter to the Secretary of the Commission at least thirty (30) days prior to consummating the proposed Agreement ("First Waiting Period"). If Respondent BMS so requests, the Commission shall keep the Notification Letter and accompanying information and documents confidential to the extent provided by law.

C. If the Notification Letter is provided pursuant to:

(1) Paragraph XII, representatives of the Commission may make a written request for additional information or documentary material (as if the request were within the meaning of 16 C.F.R. § 803.20) prior to expiration of the First Waiting Period. If such a request for additional information is made, Respondent BMS shall not execute the proposed Agreement until expiration of thirty (30) days following complete submission of such additional information or documentary material ("Second Waiting Period"). Receipt by the Commission from Respondent BMS of any notification, pursuant to this Paragraph XVI, is not to be construed as a determination by the Commission that any action described in such notification does or does not violate this Order or any law enforced by the Commission.

(2) Paragraphs X, XIV or XV, Respondent BMS may execute the proposed Agreement upon expiration of the First Waiting Period.

D. Early termination of the Waiting Periods in this Paragraph XVI may be requested from the Director of the Commission's Bureau of Competition.

XVII.

IT IS FURTHER ORDERED that Respondent BMS shall file a verified written report within sixty (60) days after the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent BMS intends to comply, is complying, and has complied with this Order. Respondent BMS shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order. As to Paragraph VII of this Order, this description shall identify all ANDAs subjected to a 30-Month Stay of FDA approval, and as to each of these 30-Month Stays, a description of BMS's efforts to comply with Paragraph VII of this Order.

XVIII.

IT IS FURTHER ORDERED that Respondent BMS shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent BMS such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent BMS that may affect compliance obligations arising out of this Order.

XIX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order and subject to any legally recognized privilege or immunity, and upon written request with reasonable notice to Respondent BMS, Respondent BMS shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession or under its control relating to compliance with this Order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondent BMS, who may have counsel present, regarding such compliance issues.

XX.

IT IS FURTHER ORDERED that this Order shall terminate on April 14, 2013.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: April 14, 2003

Exhibit C

Exhibit 99.1

Settlement Agreement

Sanofi and Apotex agree to settle the litigations between them involving U.S. Patent No. 4,847,265, 02CV-2255 and 05CV-3965, on the following terms:

1. As used herein, the term "Sanofi" refers to Sanofi-Aventis, Sanofi-Synthelabo, Inc., Bristol-Myers Squibb Company, and the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, collectively and individually, and the term "Apotex" refers to Apotex Inc. and Apotex Corp., collectively and individually, and including any entity now or hereafter owned or controlled by any of them.

2. Prior to completion of the Regulatory Review referred to in paragraph 17, the terms of this agreement are and remain confidential and will not be disclosed or used except as required by law or to effectuate the agreement, provided, however, that prior to the end of that review period, Sanofi may disclose the material terms of the agreement in anticipation of, and prior to, an official government request. If Sanofi discloses any of the terms in a manner to make them publicly available, the requirement of confidentiality as to those terms shall expire. If any party wishes to issue a press release, it will first make the text available to all other parties.

3. The pending litigations between Apotex and Sanofi will be terminated by dismissal, without prejudice, of the complaints and all counterclaims, and Apotex releases all claims that it brought or could have brought against Sanofi in connection with these litigations.

4. Apotex is granted a license, under the '265 patent, effective on September 17, 2011 to make, use, import, sell and offer for sale its clopidogrel bisulfate ANDA product in the United States but without the right to grant sub-licenses. However, if Sanofi does not obtain pediatric exclusivity for its clopidogrel bisulfate product by March 1, 2011, then Apotex's license shall become effective on March 17, 2011. If Sanofi obtains a pediatric exclusivity period that is less than 6 months, then Apotex's license shall become effective on a date which is X months earlier than September 17, 2011, where X is calculated as 6 minus the number of months for which Sanofi is granted pediatric exclusivity.

5. The license granted under paragraph 4 shall be exclusive to Apotex, for a period of 6 months except for the reserved right of Sanofi to sell its Plavix brand product, but not to launch an authorized generic.

6. If, through the action of another entity, every basis for Apotex's sole market exclusivity for clopidogrel bisulfate under 21 U.S.C. § 355(j)(5) is triggered before the date specified in paragraph 4, then the license granted to Apotex in paragraph 4 shall commence on that earlier date.

7. Apotex agrees that neither it, nor any lawyers, officers, employees, or fact or expert witnesses who are under Apotex's control will assist, encourage or provide any information to any party in attacking the '265 patent except as compelled by law. If Apotex breaches this provision, any license granted hereunder shall be non-exclusive, Sanofi will have the right to launch an authorized generic at any time, and Apotex shall not be entitled to any of the payments provided in paragraph 15.

8. If an event has occurred that Apotex, in good faith, believes poses a credible threat to constitute a trigger of every basis on which Apotex would have sole exclusivity for clopidogrel bisulfate under the Hatch-Waxman Act, Apotex shall inform Sanofi, giving Sanofi full details thereof. Sanofi shall have 30 days within which to decide whether to accelerate the effective date of Apotex's license. If Sanofi elects not to accelerate the effective date of Apotex's license, and Apotex takes all reasonable steps, as Sanofi directs and at Sanofi's expense, to contest the loss of that exclusivity, and there is a final determination that the event did cause Apotex to lose all or any portion of that exclusivity, Sanofi will compensate Apotex for the economic loss Apotex suffered as a result of the failure to accelerate Apotex's license, the amount of such loss to be determined by arbitration in New York City under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by the American Arbitration Association who shall have at least 10 years experience, with the arbitrator's fee to be shared equally by Apotex and Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment.

9. During the period that Apotex's license is exclusive, Apotex shall pay to Sanofi a royalty of 1% of its net sales on all sales of its clopidogrel bisulfate product in the United States. Sanofi shall have the right to audit Apotex's sales, using an independent auditor, and at Sanofi's expense.

10. Apotex agrees that it will not sell any clopidogrel product in the United States prior to the date its license under the '265 patent becomes effective. Apotex further agrees that any breach by it of this provision will cause irreparable harm to Sanofi. Apotex hereby irrevocably and unconditionally consents to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction to enforce this provision. Apotex irrevocably and unconditionally consents to personal jurisdiction and venue in the United States District Court for the Southern District of New York for the purpose of enforcing the provisions of this paragraph.

11. Sanofi agrees that, until and during such time as Apotex has an exclusive license under the '265 Patent, it will not launch, or authorize any other party to launch, a generic clopidogrel product in the United States. Sanofi further agrees that any breach by it of this provision will cause irreparable harm to Apotex. Sanofi hereby irrevocably and unconditionally consents to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction to enforce this provision. Sanofi irrevocably and unconditionally consents to personal jurisdiction and venue in the United States District Court for the Southern District of New York for the purpose of enforcing the provisions of this paragraph.

12. The parties understand that Sanofi may be endeavoring to reach an agreement with Dr. Reddy's Laboratories (DRL) that terminates the litigation with that company on the '265 patent. If an agreement with DRL has not been negotiated at the time that Regulatory Clearance, as defined in paragraph 17, has been obtained, then Sanofi at its sole discretion may:

1) terminate this agreement;

2) elect to continue to negotiate with DRL and not terminate this agreement;

Sanofi will inform Apotex when it has concluded an agreement with DRL.

If Sanofi elects to terminate at any time pursuant to this paragraph, or if Sanofi has not concluded an agreement with DRL by June 30, 2006, subject to extensions pursuant to paragraph 18(i), the remaining provisions of this agreement shall apply in the same manner as if Regulatory Clearance was not obtained and Apotex would be entitled to all its rights and remedies available to it as if Regulatory Denial had occurred as of the date Sanofi terminates the agreement, or the ability of Sanofi to obtain extensions under paragraph 18(i) expires.

13. As compensation to Apotex for Apotex's investment in inventory, Sanofi will reimburse Apotex for Apotex's stock of clopidogrel bisulfate bulk and finished goods that are in Apotex's actual possession as of March 31, 2006, for a price not to exceed $40 million, which Apotex represents and warrants is its actual, fully loaded cost for that inventory, as evidenced by documents Apotex will provide. That sum will be payable within 30 days after Regulatory Clearance (as defined in paragraph 17) with interest from the date of execution of this agreement at an annual interest rate of 6.5%, compounded monthly. Upon execution of this agreement, Apotex will cease writing purchase orders to Signa and will advise Signa not to ship any additional bulk clopidogrel bisulfate until further notice. Apotex will, at Sanofi's election and expense, either deliver to Sanofi, or destroy, all or any portion of that inventory, up to the value of $40 million.

14. To relieve Apotex from the risk of liability under its agreement with Signa to purchase bulk clopidogrel bisulfate, Sanofi agrees to negotiate in good faith with Signa to obtain a release, for fair value, of any claims that Signa has against Apotex under the Apotex/Signa contract dated June 30, 2000. It is understood, however, that Sanofi is not required by this provision to assume Apotex's obligations or otherwise step into Apotex's shoes under the contract. If a release has not been agreed within 90 days after Regulatory Clearance is obtained, then either Signa or Sanofi may submit the matter to binding arbitration to determine that fair value under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by AAA, who shall have at least 10 years experience, with the arbitrator's fee to be paid by Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment. If Signa refuses to accept the provisions of this paragraph, then Sanofi agrees to defend Apotex against a suit by Signa with counsel chosen by Sanofi, and (provided Sanofi controls the defense of such suit) to indemnify Apotex against any award or settlement resulting from that suit. Signa will have the right to enforce the provisions of this paragraph. Apotex will not participate in

or advise Signa in connection with the negotiations. However, Apotex may provide any information that it is requested by either Sanofi or Signa, provided Apotex provides that information equally and simultaneously to both Sanofi and Signa. Apotex warrants that neither it nor anyone affiliated with or employed by Apotex will receive directly or indirectly, any financial benefit from any settlement or agreement between Sanofi and Signa. Apotex warrants that the June 30, 2000 contract is the only agreement that Apotex has with Signa or any other supplier that relates to clopidogrel bisulfate except for an agreement dated October 15, 2000 between Brantford Chemicals Inc. and Signa, but Apotex warrants that Apotex will not receive any benefit under that agreement as the result of any negotiation or agreement between Sanofi and Signa pursuant to this paragraph.

15. If Apotex first enters the market pursuant to this agreement as approved by the FTC, Sanofi will compensate Apotex if annualized Plavix U.S. sales, determined by multiplying by four the IMS reported sales for the three months period immediately preceding Apotex's entry, are less than the minimum laid out in the following table:

Year of Apotex's Entry	Annualized Sales Minimum
2007	$ 3.8B
2008	4.1B
2009	4.3B
2010	4.7B
2011	5B

The amount of the compensation in any year will be one-half of the difference between the above minimum and the annualized IMS sales multiplied by 0.625. Such compensation will be capped at 75% of the compensation that would be due under this formula if IMS sales were $0.

16. It is expressly understood that no license is granted under any other patent owned or controlled by Sanofi.

17. This agreement is subject to regulatory review by the FTC and state attorneys general ("Regulatory Review"). The parties shall cooperate and use all reasonable efforts to facilitate the review by the FTC and state attorneys general and to respond to requests by such agencies for additional information in a timely manner. The provisions of paragraphs 3-15 of this agreement shall not be or become effective unless and until: (a) the FTC issues an advisory opinion determining that the agreement would not raise issues under Section 5 of the Federal Trade Commission Act, and (b) the state attorneys general provide written notice that they do not object to the agreement (a) and (b) together constituting "Regulatory Clearance". If the FTC, state attorneys general or other governmental agency objects to the agreement, the parties shall use reasonable efforts to continue the Regulatory Review to address such objection and to obtain

Regulatory Clearance, provided that there shall be no material change to the rights and obligations of the parties under this agreement except as they may mutually agree. "Regulatory Denial", as used herein, shall mean any of (i) a denial of approval by either of the FTC or a state attorney general as to which neither party seeks further review or (ii) Sanofi's election to terminate or not to continue (as referred to in paragraph 18(i)) the Regulatory Review or (iii) Sanofi's option to continue Regulatory Review has expired at a time when Regulatory Clearance has not been obtained or (iv) Sanofi has elected to terminate this agreement after continuing negotiations with DRL pursuant to paragraph 12.

18. In the event of Regulatory Denial, the litigations will be resumed as further described in paragraph 19 hereof, and:

(i) Sanofi will pay Apotex the sum of $60 million if Regulatory Denial occurs on or before June 30, 2006. If Regulatory Clearance has not been received by June 30, 2006, Sanofi may, at its sole discretion, either terminate the review or, after giving 30 days advance notice to Apotex, permit it to continue month–by–month, by agreeing to pay Apotex the following additional amounts, payable if and when Regulatory Denial occurs:

- To July 31, 2006, $20 million
- To August 31, 2006, $20 million
- To September 30, 2006, $30 million
- To October 31, 2006, $30 million
- To November 30, 2006, $40 million
- To December 31, 2006, $40 million

For avoidance of doubt, by way of example, the notice provision of this paragraph means that Sanofi would be required to give Apotex notice on or before June 1, 2006 in order to extend the Regulatory Review period to July 31, 2006.

In addition, Sanofi will compensate Apotex by reimbursing Apotex for its fully loaded cost for any clopidogrel bisulfate inventory in Apotex's possession that has less than one year of remaining shelf life as of the end of each of those months.

(ii) Payments defined in sub–paragraph (i) are cumulative and shall be due and payable not later than 30 days after Regulatory Denial. Any amount that is not timely paid by Sanofi shall accrue interest at the rate of 1% per month, compounded monthly.

(iii) If the litigation results in a judgment that the '265 patent is not invalid or unenforceable, Sanofi agrees that its actual damages for any past infringement by Apotex, up to the date on which Apotex is enjoined, will be 70% of Apotex's net sales of clopidogrel products if Sanofi has not launched an authorized generic and 60% of Apotex's net sales if Sanofi has launched an authorized generic. Sanofi further agrees that it will not seek increased damages under 35 U.S.C. § 284.

19. Sanofi and Apotex will jointly request that the court adjourn the presently set trial date of June 12, 2006 and adjourn all due dates, but retain jurisdiction, in the litigation between Sanofi and Apotex and DRL to permit the Regulatory Review of this agreement. If the Regulatory Review results in Regulatory Denial, Sanofi and Apotex will jointly request that the court reset the June 12, 2006 trial date to a date that is not earlier than 2 1/2 months from the date on which the request is made. Apotex agrees that it will not launch a generic clopidogrel product during the time of the Regulatory Review and Sanofi agrees it will not launch an authorized generic clopidogrel product during the time of the Regulatory Review. The parties agree that they shall jointly seek issuance of a court order embodying the provisions of this paragraph 19. Further, it is agreed that if the Regulatory Review results in Regulatory Denial then,

(i) Until 5 business days after the date on which Regulatory Denial is effective (not counting the day on which it becomes effective), Apotex will not launch a generic clopidogrel product and Sanofi will not launch an authorized generic product, and Sanofi will not seek a temporary restraining order or a preliminary injunction.

(ii) After the expiration of the period defined in sub-paragraph (i), Sanofi agrees that it will not launch an authorized generic clopidogrel product before a launch by Apotex of a generic clopidogrel product, and Sanofi will not file for a temporary restraining order or preliminary injunction until either: (1) Sanofi gives Apotex 5 business days notice (not counting the day on which notice is given) of its intention to do so; or (2) Apotex has initiated a launch of a generic clopidogrel product.

20. No provision of this agreement shall require Sanofi or Apotex to do any act that violates any term of any of the FTC consent decrees or court injunctions to which Sanofi is subject, or is otherwise unlawful.

Signed and agreed on March 17, 2006

For Apotex Inc. and Apotex Corp.	/s/ Barry Sherman
For Sanofi–Aventis	/s/ Jean–Pierre Kerjouan
For Bristol–Myers Squibb Company	/s/ Andrew G. Bodnar
For Bristol–Myers Squibb Sanofi Pharmaceuticals Holding Partnership	/s/ Andrew G. Bodnar /s/ Jean–Pierre Kerjouan

Exhibit D

Exhibit 99.2

Settlement Agreement

Sanofi and Apotex agree to settle the litigations between them involving U.S. Patent No. 4,847,265, 02CV-2255 and 05CV-3965, on the following terms:

1. As used herein, the term "Sanofi" refers to Sanofi-Aventis, Sanofi-Synthelabo, Inc., Bristol-Myers Squibb Company, and the Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, collectively and individually, and the term "Apotex" refers to Apotex Inc. and Apotex Corp., collectively and individually, and including any entity now or hereafter owned or controlled by any of them.

2. Prior to completion of the Regulatory Review referred to in paragraph 13, the terms of this agreement are and remain confidential and will not be disclosed or used except as required by law or to effectuate the agreement, provided, however, that prior to the end of that review period, Sanofi may disclose the material terms of the agreement in anticipation of, and prior to, an official government request. If Sanofi discloses any of the terms in a manner to make them publicly available, the requirement of confidentiality as to those terms shall expire. If any party wishes to issue a press release, it will first make the text available to all other parties.

3. The pending litigations between Apotex and Sanofi will be terminated by dismissal, without prejudice, of the complaints and all counterclaims, and Apotex releases all claims that it brought or could have brought against Sanofi in connection with these litigations.

4. Apotex is granted a license, under the '265 patent, effective on June 1, 2011 to make, use, import, sell and offer for sale its clopidogrel bisulfate ANDA product in the United States but without the right to grant sub-licenses and Sanofi will not waive its pediatric exclusivity with respect to any other ANDA filer prior to January 31, 2012. However, if Sanofi does not obtain pediatric exclusivity for its clopidogrel bisulfate product by March 15, 2011, then Apotex's license shall become effective on April 1, 2011.

5. In the event that Sanofi launches a drug product (other than Plavix), an active ingredient of which is an anti-platelet aggregation agent, in the United States, prior to the effective date of Apotex's license under the '265 Patent, then Apotex shall be granted a license to make, use, offer for sale, sell, and import such drug product in the United States, under all patents applicable to that drug product owned by or licensed to Sanofi, effective on the date which is the effective date of Apotex's license under the '265 Patent pursuant to this agreement.

6. If, through the action of another entity, every basis for Apotex's sole market exclusivity for clopidogrel bisulfate under 21 U.S.C. § 355(j)(5) is triggered before the date specified in paragraph 4, then the license granted to Apotex in paragraph 4 shall commence on that earlier date.

7. Apotex agrees that neither it, nor any lawyers, officers, employees, or fact or expert witnesses who are under Apotex's control will assist, encourage or provide any information to any party in attacking the '265 patent except as compelled by law.

8. If an event has occurred that Apotex, in good faith, believes poses a credible threat to constitute a trigger of every basis on which Apotex would have sole exclusivity for clopidogrel bisulfate under the Hatch–Waxman Act, Apotex shall inform Sanofi, giving Sanofi full details thereof. Sanofi shall have 30 days within which to decide whether to accelerate the effective date of Apotex's license. For purposes of this paragraph, "trigger" shall mean forfeiture, cancellation, or loss for any reason. If Sanofi elects not to accelerate the effective date of Apotex's license, and Apotex takes all reasonable steps, as Sanofi directs and at Sanofi's expense, to contest the loss of that exclusivity, and there is a final determination that the event did cause Apotex to lose all or any portion of that exclusivity, Sanofi will compensate Apotex for the economic loss Apotex suffered as a result of the failure to accelerate Apotex's license, the amount of such loss to be determined by arbitration in New York City under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by the American Arbitration Association who shall have at least 10 years experience, with the arbitrator's fee to be shared equally by Apotex and Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment.

9. Apotex agrees that it will not sell any clopidogrel product in the United States prior to the date its license under the '265 patent becomes effective. Apotex further agrees that any breach by it of this provision will cause irreparable harm to Sanofi. Apotex hereby irrevocably and unconditionally consents to immediate entry of a temporary restraining order, preliminary injunction and permanent injunction to enforce this provision. Apotex irrevocably and unconditionally consents to personal jurisdiction and venue in the United States District Court for the Southern District of New York for the purpose of enforcing the provisions of this paragraph.

10. As compensation to Apotex for Apotex's investment in inventory, Sanofi will reimburse Apotex for Apotex's stock of clopidogrel bisulfate bulk and finished goods that are in Apotex's actual possession as of March 31,2006, for a price not to exceed $40 million, which Apotex represents and warrants is its actual, fully loaded cost for that inventory, as evidenced by documents Apotex will provide. That sum will be payable within 30 days after Regulatory Clearance (as defined in paragraph 13) with interest from the date of execution of this agreement at an annual interest rate of 6.5%, compounded monthly. Upon execution of this agreement, Apotex will cease writing purchase orders to Signa and will advise Signa not to ship any additional bulk clopidogrel bisulfate until further notice. Apotex will, at Sanofi's election and expense, either deliver to Sanofi, or destroy, all or any portion of that inventory, up to the value of $40 million.

11. To relieve Apotex from the risk of liability under its agreement with Signa to purchase bulk clopidogrel bisulfate, Sanofi agrees to negotiate in good faith with Signa to obtain a release, for fair value, of any claims that Signa has against Apotex under the Apotex/Signa contract dated June 30, 2000. It is understood, however, that Sanofi is not required by this provision to assume Apotex's obligations or otherwise step into Apotex's shoes under the contract. If a release has not been agreed within 90 days after Regulatory Clearance is obtained, then either Signa or Sanofi may submit the matter to binding arbitration to determine that fair value under the commercial arbitration rules of the American Arbitration Association, using a single arbitrator chosen by AAA, who shall have at least 10 years experience, with the arbitrator's fee to be paid by Sanofi. If possible, the first meeting with the arbitrator shall take place within one month of his/her appointment. If Signa refuses to accept the provisions of this paragraph, then Sanofi agrees to defend Apotex against a suit by Signa with counsel chosen by Sanofi, and (provided Sanofi controls the defense of such suit) to indemnify Apotex against any award or settlement resulting from that suit. Signa will have the right to enforce the provisions of this paragraph. Apotex will not participate in or advise Signa in connection with the negotiations. However, Apotex may provide any information that is requested by either Sanofi or Signa, provided Apotex provides that information equally and simultaneously to both Sanofi and Signa. Apotex warrants that neither it nor anyone affiliated with or employed by Apotex will receive directly or indirectly, any financial benefit from any settlement or agreement between Sanofi and Signa. Apotex warrants that the June 30, 2000 contract is the only agreement that Apotex has with Signa or any other supplier that relates to clopidogrel bisulfate except for an agreement dated October 15, 2000 between Brantford Chemicals Inc. and Signa, but Apotex warrants that Apotex will not receive any benefit under that agreement as the result of any negotiation or agreement between Sanofi and Signa pursuant to this paragraph.

12. It is expressly understood that, except as provided in paragraph 5 above, no license is granted under any other patent owned or controlled by Sanofi.

13. This agreement is subject to regulatory review by the FTC and state attorneys general ("Regulatory Review"). The parties shall cooperate and use all reasonable efforts to facilitate the review by the FTC and state attorneys general and to respond to requests by such agencies for additional information in a timely manner. The provisions of paragraphs 3–12 of this agreement shall not be or become effective unless and until: (a) the FTC issues an advisory opinion determining that the agreement would not raise issues under Section 5 of the Federal Trade Commission Act, and (b) the state attorneys general provide written notice that they do not object to the agreement, (a) and (b) together constituting "Regulatory Clearance". If the FTC, state attorneys general or other governmental agency objects to the agreement, the parties shall use reasonable efforts to continue the Regulatory Review to address such objection and to obtain Regulatory Clearance, provided that there shall be no material change to the rights and obligations of the parties under this agreement except as they may mutually agree. "Regulatory Denial", as used herein, shall mean a denial of approval by

either of the FTC or a state attorney general as to which neither party seeks further review. If Regulatory Review has not been completed by July 31, 2006, either party has the right to declare that there has been Regulatory Denial.

14. In the event of Regulatory Denial, the litigations will be resumed as further described in paragraph 15 hereof, and:

(i) Sanofi will compensate Apotex by reimbursing Apotex for its fully loaded cost for any clopidogrel bisulfate inventory in Apotex's possession that has less than one year of remaining shelf life as of the end of each of those months, provided, however, that Apotex shall relabel its inventory to the extent possible to extend its expiration date, and Sanofi shall pay Apotex an amount not to exceed $500,000 to effectuate that relabelling.

(ii) If the litigation results in a judgment that the '265 patent is not invalid or unenforceable, Sanofi agrees that its actual damages for any past infringement by Apotex, up to the date on which Apotex is enjoined, will be 50% of Apotex's net sales of clopidogrel products if Sanofi has not launched an authorized generic and 40% of Apotex's net sales if Sanofi has launched an authorized generic. Sanofi further agrees that it will not seek increased damages under 35 U.S.C.§284.

15. Sanofi and Apotex will jointly request that the court maintain the litigation between them on the court's suspense docket to permit the Regulatory Review of this agreement. If the Regulatory Review results in Regulatory Denial, Sanofi and Apotex will jointly request that the court reset the trial date to a date that is not earlier than 2 1/2 months from the date on which the request is made. Apotex agrees that it will not launch a generic clopidogrel product during the time of the Regulatory Review and Sanofi agrees it will not launch an authorized generic clopidogrel product during the time of the Regulatory Review. The parties agree that they shall jointly seek issuance of a court order embodying the provisions of this paragraph. Further, it is agreed that if the Regulatory Review results in Regulatory Denial then,

(i) Until 5 business days after the date on which Regulatory Denial is effective (not counting the day on which it becomes effective), Apotex will not launch a generic clopidogrel product and Sanofi will not launch an authorized generic product, and Sanofi will not seek a temporary restraining order or a preliminary injunction.

(ii) After the expiration of the period defined in sub-paragraph (i), Sanofi agrees that it will not launch an authorized generic clopidogrel product before a launch by Apotex of a

generic clopidogrel product, and Sanofi will not, at any time, file for a temporary restraining order, and will not file for a preliminary injunction until Sanofi gives Apotex 5 business days notice (not counting the day on which notice is given) of its intention to do so, which notice will not be given before Apotex has initiated a launch of a generic clopidogrel product.

16. No provision of this agreement shall require Sanofi or Apotex to do any act that violates any term of any of the FTC consent decrees or court injunctions to which Sanofi is subject, or is otherwise unlawful

17. This agreement may be executed in counterparts by each of the parties hereto.

Signed and agreed on May 26, 2006

For Apotex Inc. and Apotex Corp.	/s/ Barry Sherman
For Sanofi–Aventis	/s/ Jean–Pierre Kerjouan
For Bristol–Myers Squibb Company	/s/ Andrew G. Bodnar
For Bristol–Myers Squibb Sanofi Pharmaceuticals Holding Partnership	/s/ Andrew G. Bodnar /s/ Jean–Pierre Kerjouan

Exhibit E

THE COMMONWEALTH FUND

TASK FORCE ON THE FUTURE OF HEALTH INSURANCE

Issue Brief

FEBRUARY 2004

Lack of Prescription Coverage Among the Under 65: A Symptom of Underinsurance

CLAUDIA L. SCHUR, MICHELLE M. DOTY, AND MARC L. BERK

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Prescription drugs are playing an increasingly greater role in the health care delivery system: not only are more Americans using prescription medicines than ever before, but the number of prescriptions per user has increased as has the number of days of therapy per prescription.[1] Between 1977 and 1998, the proportion of Americans taking at least one prescription rose from 58 to 66 percent and the average number of prescriptions per person more than doubled.[2] The daily cost of using drugs also has increased due to the higher cost of new drug therapies, inflation in the cost of older drugs, and a change in the mix of drugs prescribed.

Recent examinations of national health expenditures find that spending on prescription drugs rose 15.3 percent in 2002, to $162 billion.[3] In 2002, expenditures on prescription drugs accounted for 12.1 percent of personal health care spending, up from 8.6 percent in 1988. Since 1993, average annual rates of growth for spending on drugs have been 10 percent or greater, with growth in spending on drugs leading all other health care services in 2001 and 2002.

This increased use and spending have garnered policy attention, largely centered on the elderly because of the political push to add an outpatient Medicare prescription drug benefit. Yet prescription drug benefits are of concern to the under-65 population as well. Findings from this study indicate that lacking drug benefits is a form of underinsurance: nonelderly adults who have health insurance but no drug

benefit are at risk for high out-of-pocket costs and burdensome medical bills—the kinds of problems typically observed among uninsured populations.

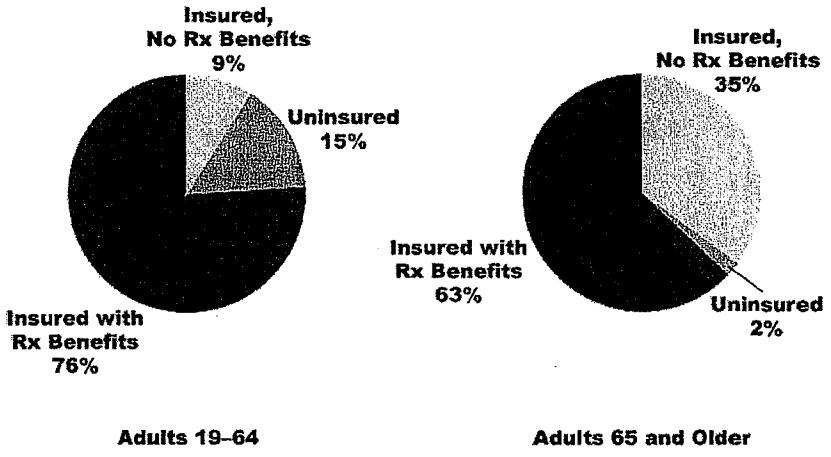
The issue brief draws on a 2001 national survey to compare cost-related access problems and medical bill burdens of nonelderly and elderly insured adults, with and without drug coverage. We find that one of three (35%) insured adults 65 and older lacks a prescription drug benefit. But nearly one of 10 (9%) insured adults under 65 also has no coverage for drugs. The findings indicate that adults under 65 who are insured but lack prescription benefits are at high risk of going without needed care. Like their elderly counterparts, they often face high out-of-pocket costs and burdensome medical bills. Thus, for the under-65 population, the lack of a drug benefit may be an indicator of inadequate insurance coverage—one of the more visible signs that a plan has holes in basic coverage. Low-income adults are at greatest risk for inadequate coverage. These findings highlight the need to consider the content and comprehensiveness of insurance in discussions about possible reforms to expand or improve health insurance coverage for the working-age population.

★ ★ ★ ★ ★

Findings

In 2001, 9 percent of the nonelderly adult population—an estimated 14 million people—were insured but lacked prescription drug coverage, while 15 percent of this population lacked health insurance altogether (Figure 1). While the majority (76%) of nonelderly adults were insured with prescription drug benefits, far fewer seniors (63%) had insurance with prescription drug coverage. More than one-third (35%) of adults 65 and older lacked a prescription benefit.

Distribution of Prescription Drug Benefits Among Elderly and Nonelderly Adults, 2001 Figure 1



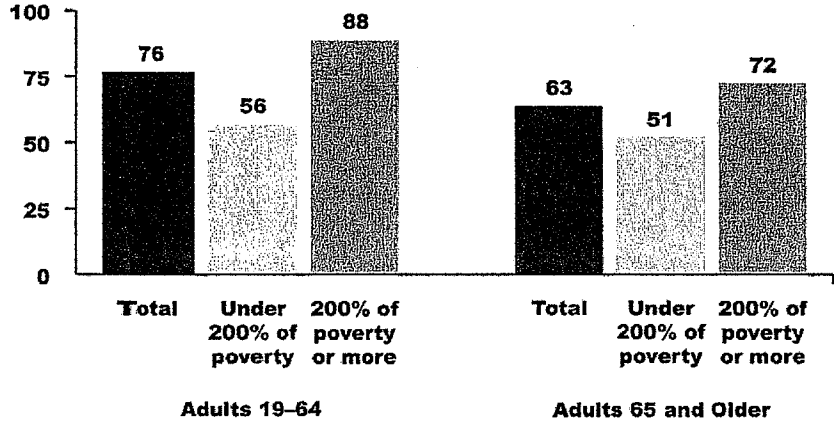
Source: The Commonwealth Fund 2001 Health Insurance Survey.

Drug coverage rates among the insured generally were high, but low-income populations (those with incomes below 200 percent of poverty) were least likely to have drug benefits—or have any insurance at all.[4] Just 56 percent of low-income nonelderly adults and 51 percent of low-income seniors had prescription drug benefits (Figure 2).

Cost-Related Access Problems

Among nonelderly adults, being insured without drug benefits increases the likelihood of going without prescription drugs and forgoing other needed health care. Insured adults 19 to 64 years without drug coverage are nearly twice as likely as those with drug coverage to report having not filled a prescription due to cost (28% vs. 16%) (Figure 3).[5] Despite having insurance coverage for other medical expenses, adults without drug benefits are significantly more likely than those with drug benefits to skip recommended tests or follow-up care (24% vs. 11%) or forgo seeing a doctor

Low-Income Adults Are Less Likely to Have Prescription Drug Benefits Figure 2



Source: The Commonwealth Fund 2001 Health Insurance Survey.

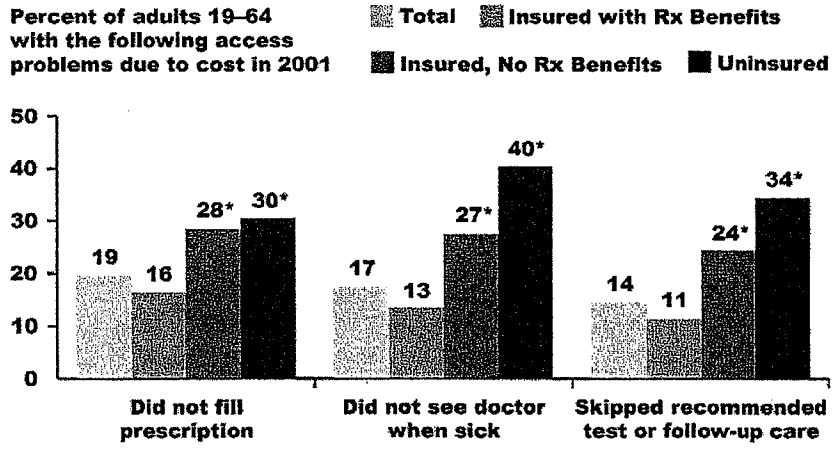
when sick (27% vs. 13%) because of cost.[6] Rates of not filling prescriptions among insured adults without drug benefits were similar to those reported by uninsured adults. But uninsured adults forgo other kinds of health care because of cost at significantly higher rates than other groups.

By contrast, among the elderly, differences between those with and without drug coverage reporting cost-related access problems are not statistically significant. Yet, differences still emerge: 14 percent of the elderly without drug coverage did not fill a prescription because of cost, compared with 9 percent of seniors with drug coverage.

Financial Burdens for Those Without Drug Benefits

Those without drug coverage not only forgo needed care, but face burdensome medical bills and high out-of-pocket expenses when they do receive care. Nonelderly adults without drug coverage are significantly more likely than those with such coverage to have problems paying medical bills, even after taking into account income and health status. Thirty percent of those without drug coverage reported such a problem, compared with just 23 percent of those with coverage (Figure 4). The uninsured are particularly at risk, with nearly half (47%) reporting that they were unable to pay for medical bills. One of five (21%) nonelderly adults without drug coverage reported having to change their way of life significantly to pay medical bills, compared with just 13 percent of adults with drug coverage. Not surprisingly, out-of-pocket expenses on prescription drugs are generally much higher for those who have no third-party coverage for drugs. One-quarter (26%) of nonelderly adults without drug benefits had out-of-pocket expenses that constituted 5 percent or more of their annual income, whereas only

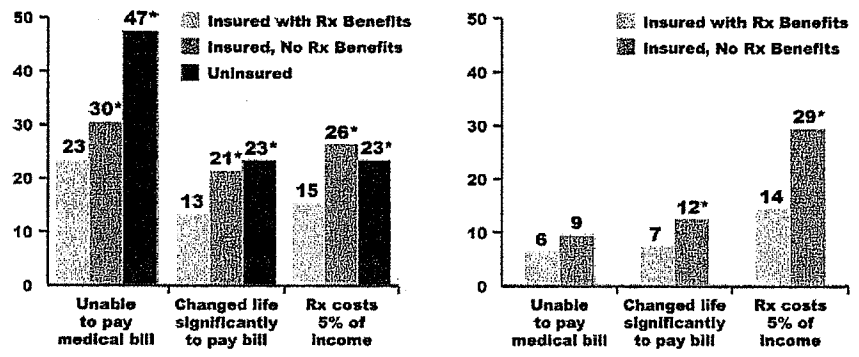
Access Problems Are Greatest for Those Without Prescription Drug Coverage or Insurance Figure 3



Note: Adjusted percentages controlling for poverty and health status.
* Indicates significant differences between those insured with Rx benefits at $p < .001$.
Source: The Commonwealth Fund 2001 Health Insurance Survey.

Figure 4

Medical Bill Problems and High Out-of-Pocket Costs Are Greatest for Adults Without Drug Benefits and the Uninsured



Note: Adjusted percentages controlling for poverty and health status.
* Indicates significant differences between those insured with Rx benefits at $p < .05$.
Source: The Commonwealth Fund 2001 Health Insurance Survey.

15 percent of adults with coverage reported such expenses.

Despite their Medicare coverage, seniors without drug coverage also face medical bill problems and high out-of-pocket expenses. Twelve percent of seniors without drug benefits reported having to change their way of life significantly to pay their medical bills, compared with just 7 percent of those with drug coverage. Even after adjusting for income and health status, 29 percent of seniors without coverage spent at least 5 percent of their income on drug costs, compared with just 14 percent of seniors with drug benefits.

Lacking Drug Coverage Is an Indicator of Other Health Plan Problems

The insured with prescription drug coverage are more likely than those without such coverage to rate their insurance plan favorably—21 percent of 19- to 64-year-old adults with drug coverage and 35 percent of seniors with drug coverage said their insurance was excellent (Table 1). By contrast, 14 percent of working-age adults without drug coverage and 25 percent of the elderly without such coverage rated their plans as excellent. Even after adjusting for income and health status, differences between those with and without drug coverage remain statistically significant. Not having drug coverage appears to be related to other insurance problems. Overall, 61 percent of the nonelderly without drug coverage reported at least one insurance problem, compared with 45 percent of the nonelderly with coverage. Among the elderly, 49 percent of those without drug coverage had at least one insurance problem, while just 29 percent of those with drug coverage reported at least one such problem.

In general, the nonelderly are less satisfied with their health plans than are the elderly. A previous study found that Medicare beneficiaries (65 and older) were more likely than adults 19 to 64 enrolled in employer-sponsored plans to rate their health insurance as excellent (32% vs. 20%), and less likely to report negative experiences with their plans (43% vs. 61%), even after adjusting for health status and income.[7]

Discussion

Rising health care costs and the need to contain these costs have led to policy debates of what constitutes a basic health insurance package. Our findings indicate that the absence of drug benefits is a marker of inadequate insurance coverage for nonelderly as well as elderly adults. Adults without drug benefits face financial burdens in purchasing prescription pharmaceuticals and are significantly more likely to face high out-of-pocket costs relative to their incomes. Furthermore, those who have insurance but lack drug benefits are more likely to go without needed medical care beyond medications and, in general, are more likely to rate their insurance negatively. This absence of drug

Table 1. Satisfaction and Confidence Experiences with Insurance Plan Among Insured Adults with or Without Prescription Coverage, 2001

		AGE 19–64		AGE 65+	
	Total	With Prescription	Without Prescription	With Prescription	Without Prescription
Rating of Insurance					
Excellent	23%	21%	14%*	35%	25%*
Very good	32	33	19	35	29
Good	26	26	28	15	26
Fair/Poor	19	18	34	11	19
Problems with Insurance Plan					
Plan did not pay anything for care respondent thought was covered	21	23	27*	8	12
Reached limit on what plan paid for specific illness/injury	10	11	18*	‡	‡
Paid a lot out-of-pocket for Rx or dental	36	36	51*	21	45*
Had difficulty getting referral to specialist	9	10	11	‡	‡
Any one of above problems	44	45	61*	29	49*
No problems with insurance plan	45	52	37*	64	44*

* Significantly different from those with drug coverage at $p < .05$. ‡ Cell sizes too small to permit meaningful comparison.
Source: The Commonwealth Fund 2001 Health Insurance Survey.

benefits appears to be one of the more visible signs of other holes in insurance benefits. Adults with employment-related coverage and those with higher family incomes are most likely to have other types of supplemental coverage, including drug, dental, and vision. These more comprehensive policies likely account for the higher satisfaction levels and lower incidence of access problems and medical bill concerns.

Public and policy attention has focused mainly on the health and financial burdens faced by Medicare beneficiaries (65 and older) without drug benefits. Yet, this study indicates that nonelderly adults who lack drug benefits or are uninsured are at high risk for such burdens as well. As drug prices and private health insurance premiums continue to rise and states face the worst budget deficits in years, private insurance programs and Medicaid programs alike have been cutting back on the scope of benefits and instituting increases in patient cost-sharing, including multi-tiered copayment structures for drugs.[8] Reductions in benefits—including the possible spread of policies without a basic drug benefit—are likely to increase the unmet needs and financial burdens among the under-65 population, especially those with lower incomes.

If inadequate coverage results in patients cutting corners, including taking less medication than prescribed or not filling prescriptions for essential drugs, then patients' short- and long-term health may be adversely affected. Furthermore, reductions in the use of essential drugs may lead to a greater use of emergency departments or increased hospitalizations—thus raising overall health care costs.[9]

These findings have implications for future policy reforms aimed at expanding coverage to the uninsured, including efforts to provide premium assistance or tax credits to make coverage more affordable. They point to the need to attend to the content of insurance benefits—not just whether or not individuals are insured. The scope of basic benefits, including prescription drugs, will matter if the policy goal is to improve access to care and reduce the likelihood of unaffordable medical bills.

NOTES

1 S. S. Wallack et al., *Recent Trends in Prescription Drug Spending for Insured Individuals Under 65 and Age 65 and Older* (Waltham, Mass.: Schneider Institute for Health Policy, Brandeis University, July 30, 2001).

2 J. Moeller and H. Levy, *Prescribed Medicines in Ambulatory Care Settings: A Comparison of Use, Expenditures, and Sources of Payment, 1977 and 1987,* AHCPR Pub. No. 95-0062 (June 1995); *National Medical Expenditure Survey Research Findings 24* (Rockville, Md.: Agency for Health Care Policy and Research, Public Health Service); *Center on an Aging Society Data Profile Number 5, Prescription Drugs* (September 2002).

3 S. Heffler et al., "Health Spending Projections Through 2013," *Health Affairs* Web Exclusive (February 11, 2004): W4-79–W4-93.

4 Thirty percent of low-income nonelderly adults did not have any insurance in 2001. L. Duchon et al., *Security Matters: How Instability in Health Insurance Puts U.S. Workers at Risk* (New York: The Commonwealth Fund, December 2001).

5 Estimates are adjusted percentages, controlling for poverty and health status. Odds ratio not shown.

6 Ibid.

7 K. Davis et al., "Medicare Versus Private Insurance: Rhetoric and Reality," *Health Affairs* Web Exclusive (October 9, 2002): W311–W324.

8 Forty-five states are making changes to their prescription drug coverage for FY 2003, including increasing the need for prior authorization and new or higher copayments. V. Smith et al., *Medicaid Spending Growth: A 50 State Update for FY 2003,* Issue Paper (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, January 2003); J. Gabel et al., "Health Benefits in 2003: Premiums Reach Thirteen-Year High as Employers Adopt New Forms of Cost-Sharing," *Health Affairs* 22 (September/October 2003): 117–26.

9 R. Tamblyn et al., "Adverse Events Associated with Prescription Drug Cost-Sharing Among Poor and Elderly Persons," *Journal of the American Medical Association* 285 (January 24/31, 2001): 421–29.

SURVEY DESCRIPTION AND METHODS

Data come from the Commonwealth Fund 2001 Health Insurance Survey, conducted from April 27 to July 29, 2001, among 3,508 adults ages 19 and older living in households with a telephone and within the continental United States. The survey consisted of 25-minute telephone interviews either in English or Spanish. The overall survey response rate was 54 percent.

The sample is restricted to 2,829 adults ages 19–64 and 628 adults 65 and older. Respondents not reporting their age were dropped from the analysis. The final sample is weighted to the U.S. population based on age, sex, race/ethnicity, education, household size, geographic region, and telephone service interruption using the U.S. Census Bureau's March 2000 Current Population Survey.

In order to understand differences in the characteristics and experiences of those with and without prescription drug coverage, multivariate models were estimated that control for income and burden of illness (defined as reporting fair or poor health status, a disability, or a chronic health condition). The adjusted percentages presented in Figures 3 and 4 take into account the underlying differences in poverty and health status between individuals with and without prescription drug coverage.

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